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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,790	02/08/2002	Alison A. McCormick	42254	3922

27860 7590 06/27/2006

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EXAMINER

AEDER, SEAN E

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

*Supplemental*  
**Notice of Allowability**

Application No.

10/067,790

Examiner

Sean E. Aeder, Ph.D.

Applicant(s)

MCCORMICK ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendments filed on 11/22/05 and Examiner Amendment.

2. ☒ The allowed claim(s) is/are 51, 53, 54, 58-67.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John Tarcza on 6/19/06.

Lines 3-4 on page 14 of the application have been amended as follows:

(b) fused in frame to (a), a nucleic acid sequence or sequences encoding the ~~polypeptide of any of claims 1-15~~ a polypeptide self-antigen useful as a tumor-specific vaccine in a subject with a tumor or at risk of developing a tumor, encoded at least in part by a nucleic acid in the cells of said tumor, which polypeptide: (a) includes an epitope or epitopes unique to, or overexpressed by, cells of said tumor, thereby distinguishing said tumor from all other tumors (i) of the same or different histological type, (ii) in said subject or in another member of said subject's species; (b) is produced in a cell or organism that has been transformed or transfected with said nucleic acid derived from said tumor of said subject; (c) is obtainable from said cell or organism in correctly folded form, without a need for denaturation and renaturation and mimics said epitope or epitopes in their native form; (d) is capable of inducing an immune response in a mammal, including said subject, without a need for adjuvant or other immunostimulatory materials, so that administration of said polypeptide results in an

antibody or cell-mediated immune response to said epitope or epitopes, the same polypeptide produced in a plant, the same polypeptide produced transiently in the transformed or transfected plant, the same polypeptide having at least two peptide domains, the same polypeptide wherein the tumor is a B-cell lymphoma and the tumor epitope is a surface immunoglobulin epitope, the same polypeptide that includes at least one idiotypic epitope of the V region of the immunoglobulin, the same polypeptide with two V region domains of the immunoglobulin, the same polypeptide wherein the two domains are at least part of the V<sub>H</sub> and at least part of the V<sub>L</sub> domains of said immunoglobulin, the same polypeptide wherein the part of the V<sub>H</sub> region includes at least one complementarity-determining region (CDR), the same polypeptide wherein the CDR is CDR2, the same polypeptide that is a two-domain single chain antibody (scFv) that includes at least part of the V<sub>H</sub> and the V<sub>L</sub> domains, the same polypeptide that includes the V<sub>H</sub> and the V<sub>L</sub> domains, the same polypeptide wherein the domains are linked by an amino acid linker that (a) has between one and about 50 residues; (b) consists of between one and 12 different amino acids, and (c) facilitates secretion and correct folding of said polypeptide to mimic the tumor epitope in its native form in or on said tumor cell, the same polypeptide wherein the linker is a member of a randomized library of linkers that vary in size and sequence, and said library is encoded by nucleic acid sequences consisting of a repeated pattern of degenerate repeated triplet nucleotides having the following requirements; (i) position 1 of each repeated triplet cannot be the same nucleotide as position 2 of the repeated triplet; (ii) position 2 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet;

or (iii) position 1 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet, or the same polypeptide wherein the nucleotide in the first and second positions of each repeated triplet is selected from any two of deoxyadenosine, deoxyguanosine, deoxycytidine or deoxythymidine;

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SEA

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER